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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,924	03/14/2002	Daniel Albert Wettstein	1909.03	2745

26698 7590 08/18/2004

MYRIAD GENETICS INC.
LEGAL DEPARTMENT
320 WAKARA WAY
SALT LAKE CITY, UT 84108

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/14.

Office Action Summary

Application No.	Applicant(s)	
10/099,924	WETTSTEIN ET AL.	
Examiner	Art Unit	
Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 4, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-37 and 39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Please note the Examiner of record has changed. Contact information is provided at the close of this Action.
2. The Examiner notes Applicants' election of Group I (claims 1-5, 11-26 and 39) with species, DNA helicase II in the Paper received June 4, 2004. Upon reconsideration the current Examiner is setting forth a new restriction requirement.
3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - 1-7. Claims 1-5, 7 and 39, drawn to an isolated protein complex having a first protein, which is survivin interacting with a second protein, which is a protein, selected from the group consisting of cytoplasmic dynein light chain 1 (HDLC1);
beta-actin;
ATP-dependent DNA helicase II 70 kD subunit (DNA helicase II);
beta-prime subunit of coatamer complex (COPP);
osteopontin, alternate transcript 1 (OSTP);
Na⁺/Ca²⁺-exchange protein 1 (SLC8A1); and
catenin, alpha 2 (A2-CAT), respectively, classified in class 530, subclass 350.

Art Unit: 1642

8-14. Claim 6, drawn to a protein array comprising the protein complex consisting of a first protein which is survivin interacting with a second protein which is a HDLC1;

protein complex consisting of a first protein which is survivin interacting with a second protein which is beta-actin;

protein complex consisting of a first protein which is survivin interacting with a second protein which is DNA helicase II;

protein complex consisting of a first protein which is survivin interacting with a second protein which is COPP;

protein complex consisting of a first protein which is survivin interacting with a second protein which is OSTP;

protein complex consisting of a first protein which is survivin interacting with a second protein which is SLC8A1; and

protein complex consisting of a first protein which is survivin interacting with a second protein which is A2-CAT, respectively, classified in class 436, subclass 518.

15-21. Claims 8 and 27-34, drawn to a composition comprising host cells and vectors having nucleic acid encoding the fusion protein having a first polypeptide covalently linked to a second polypeptide, wherein said first polypeptide is survivin and the second polypeptide is HDLC1;

a first polypeptide covalently linked to a second polypeptide, wherein said first polypeptide is survivin and the second polypeptide is beta-actin;

a first polypeptide covalently linked to a second polypeptide, wherein said first polypeptide is survivin and the second polypeptide is DNA helicase II;

a first polypeptide covalently linked to a second polypeptide, wherein said first polypeptide is survivin and the second polypeptide is COPP;

a first polypeptide covalently linked to a second polypeptide, wherein said first polypeptide is survivin and the second polypeptide is OSTP;

a first polypeptide covalently linked to a second polypeptide, wherein said first polypeptide is survivin and the second polypeptide is SLC8A1; and

a first polypeptide covalently linked to a second polypeptide, wherein said first polypeptide is survivin and the second polypeptide is A2-CAT, respectively, classified in class 536, subclass 23.4.

22-28. Claims 9-26, drawn to a method for selecting modulators of the protein complex wherein the first protein is survivin which interacts with a second protein which is HDLC1;

the first protein is survivin which interacts with a second protein which is beta-actin;

the first protein is survivin which interacts with a second protein which is DNA helicase II;

the first protein is survivin which interacts with a second protein which is COPP;

the first protein is survivin which interacts with a second protein which is OSTP;

the first protein is survivin which interacts with a second protein which is SLC8A1; and

the first protein is survivin which interacts with a second protein which is A2-CAT, respectively, classified in class 435, subclass 7.1.

29-35. Claims 35 -37, drawn to a method for providing modulators comprising providing atomic coordinates and generating a data set defining a three-dimensional structure of the protein complex wherein, the first protein is survivin which interacts with a second protein which is HDLC1;

the first protein is survivin which interacts with a second protein which is beta-actin;

the first protein is survivin which interacts with a second protein which is DNA helicase II;

the first protein is survivin which interacts with a second protein which is COPP;

the first protein is survivin which interacts with a second protein which is OSTP;

the first protein is survivin which interacts with a second protein which is SLC8A1; and

the first protein is survivin which interacts with a second protein which is A2-CAT, respectively, classified in class 702, subclass 27.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-7 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, Groups 1-7 are drawn to protein complexes that are different polypeptide combinations. While the first protein must be survivin the group consisting of the seven different second proteins are distinct in structure and function and the search of one would not be the search of the other. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

Inventions 15-21 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups 15-21 encode structurally and functionally different protein products. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

Inventions 1-7, 8-14 and 15-21 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP

§ 806.04, MPEP § 808.01). In the instant case the different inventions are all products: protein complexes, protein arrays and nucleic acid compositions, which are distinct and unique from one another, which are made which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

Inventions 1-7, 22-28 and 29-35 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the different and distinct protein complexes of Groups 1-7 can be used in the different method groups, Group of 22-28 and Group 29-35.

Inventions 1-7, 22-28 and 35-37 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein complexes of Groups 1-7 could be used in the methods of either Groups 22-28 or Groups 35-37, as well as in *in vivo* stimulation of the immune system.

Inventions 22-28 and 29-35 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they

have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups 22-28 and 29-35 utilize patentably distinct products in patentably distinct methods. The implementation of each method with the different protein complexes will yield a different effect and endpoint. Each method requires a different amino acid sequence, which is encoded by a distinct and separate polynucleotide sequences. Ultimately the search of any of the methods of Groups 22-28 and Groups 29-35 would not be a search of another method group. Furthermore, Groups 22-28 detect the interaction between the first protein and second protein within a cellular environment, whereas the methods of Groups 29-35 select for compounds capable of modulating the interaction between the first protein and second protein based on employing atoms and molecular simulation.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. A telephone call was made to Jay Z. Zhang on 17 August 2004 to request an oral election to the above restriction requirement, but did not result in an election being made. The Examiner attempted to leave a voice mail for Mr. Zhang, however the telephone system did not allow.

Art Unit: 1642

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER



Alana M. Harris, Ph.D.
16 August 2004